

MAR 2 5 2004  
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Li et al. ) Group Art Unit: 1635  
Serial No.: 10/038,984 ) Examiner: K. Lacourciere  
Confirmation No.: 9705 ) Docket No.: 275.00030102  
Filed: January 4, 2002 )  
For: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE  
EXPRESSION USING DOUBLE STRANDED RNA

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

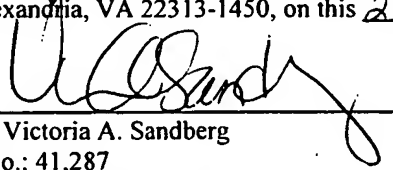
- ☒ Small entity status is entitled to be asserted in the above-identified application.  
☒ An itemized return postcard.  
☐ A Petition for Extension of Time for \_\_ month(s) and a check in the amount of \$\_\_ for the required fee.  
☒ A Supplemental Information Disclosure Statement (2 pgs); copies of 0 applications; 1449 forms (8 pgs);  
and copies of 85 documents cited on the 1449 forms.  
☐ Other: \_\_\_\_  
☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$145 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23<sup>rd</sup> day of March, 2004.

MUETING, RAASCH & GEBHARDT, P.A.  
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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)



PATENT  
Docket No. 275.00030102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): <del>Li et al.</del>	)	Group Art Unit:	1635
	)		
Serial No.: 10/038,984	)	Examiner:	K. Lacourciere
Confirmation No.: 9705	)		
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For:		COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED RNA	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

**Supplemental Information Disclosure Statement**

Page 2 of 2

Applicant(s): Li et al.

Serial No.: 10/038,984

Confirmation No.: 9705

Filed: 4 January 2002

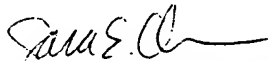
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The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23<sup>rd</sup> day of March, 2004.



W. SARA E. NELSON

March 23, 2004  
Date

Respectfully submitted for

Li et al.

By

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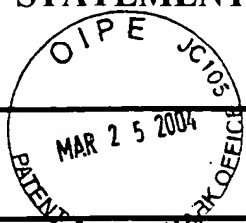
By: 

Victoria A. Sandberg

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Direct Dial (612)305-1226

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	<b>Information Disclosure Statement mailed:</b> March <u>23</u> , 2004	



## U.S. PATENT DOCUMENTS

Examiner Initial	Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,897,355	01/30/90	Eppstein et al.			
		5,107,065	04/21/92	Shewmaker et al.			
		5,264,618	11/23/93	Felgner et al.			
		5,279,833	01/18/94	Rose			
		5,283,184	02/01/94	Jorgensen et al.			
		5,283,185	02/01/94	Epand et al.			
		5,459,127	10/17/95	Felgner et al.			
		5,583,021	12/10/96	Dougherty et al.			
		5,837,533	11/17/98	Boutin			
		5,922,602	07/13/99	Kumagai et al.			
		5,932,241	08/03/99	Gorman			
		6,127,170	10/03/00	Boutin			
		5,981,505	11/09/99	Weiner et al.			
		6,217,900	04/17/01	Ciccarelli et al.			
		6,482,804	11/19/02	Musunuri et al.			
		6,506,559	01/14/03	Fire et al.			
		US 2002/0114784 A1	08/22/02	Li et al.			
		US 2002/0173478 A1	11/21/02	Gerwitz et al.			
		US 2002/0162126 A1	10/31/02	Beach et al.			
		US 2003/0056235 A1	03/20/03	Fire et al.			
		US 2003/0051263 A1	03/13/03	Fire et al.			
		US 2003/0084471 A1	05/01/03	Beach et al.			
		US 2003/0180756 A1	09/25/03	Shi et al.			

<b>EXAMINER</b>	<b>Date Considered</b>
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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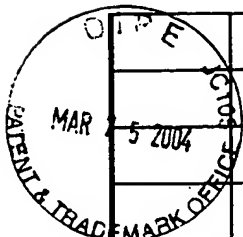
Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		US 2003/0157030 A1	08/21/03	Davis et al.			
		US 2003/0228691 A1	12/11/03	Lewis et al.			
		US 2003/0027783 A1	02/06/03	Zernicka-Goetz et al.			
		US 2004/0018999 A1	01/29/04	Beach et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	X	AU 199919380	07/12/99	Australia				
	X	AU 199929163	10/18/99	Australia				
	X	DE 101 00586	04/11/02	Germany (incl. English Abstract)				
	X	EP 0242016	10/21/87	Europe				
	X	WO 96/20951	07/11/96	PCT				
	X	WO 97/35965	10/02/97	PCT				
	X	WO 97/48793	12/24/97	PCT				
	X	WO 98/05770	02/12/98	PCT				
	X	WO 98/36083	08/20/98	PCT				
	X	WO 99/61636	12/02/99	PCT				
	X	WO 99/49029	09/30/99	PCT				
	X	WO 99/53050	10/21/99	PCT				
	X	WO 99/32619	07/01/99	PCT				
	X	WO 00/01846	01/13/00	PCT				
	X	WO 00/44895	08/03/00	PCT (incl. English Abstract)				
	X	WO 00/44914	08/03/00	PCT				

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X	WO 00/49035	08/24/00	PCT				
X	WO 00/63364	10/26/00	PCT				
X	WO 01/29058	04/26/01	PCT				
X	WO 01/36646	05/25/01	PCT				
X	WO 01/75164	10/11/01	PCT				
X	WO 01/68836	09/20/01	PCT				
X	WO 01/88121	11/21/01	PCT				

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copy Enclosed	Document Description
	X	Angell et al., "Consistent gene silencing in transgenic plants expressing a replicating potato virus X RNA," <i>EMBO J.</i> , 1997;16(12): 3675-3684.
	X	Bahramian et al., "Transcriptional and Posttranscriptional Silencing of Rodent $\alpha 1(I)$ Collagen by a Homologous Transcriptionally Self-Silenced Transgene," <i>Molecular and Cellular Biology</i> , Jan 1999;19(1): 274-283.
	X	Baulcombe, David C., "Gene Silencing: RNA makes RNA makes no protein," <i>Current Biology</i> , 1999;9: R599-R601.
	X	Baulcombe, David C., "Mechanisms of Pathogen-Derived Resistance to Viruses in Transgenic Plants," <i>The Plant Cell</i> , October 1996;8: 1833-1844.
	X	Baulcombe et al., "Ectopic pairing of homologous DNA and post-transcriptional gene silencing in transgenic plants," <i>Plant Biotechnology</i> , 1996;7: 173-180.
	X	Benfey et al., "Regulated Genes in Transgenic Plants," <i>Science</i> , 14 April 1989;244: 174-181.
	X	Branch, Andrea D., "A good antisense molecule is hard to find," <i>Trends in Biochem. Sci.</i> , February 1998;23:45-50.
	X	Bruening, G., "Plant gene silencing regularized," <i>Proc. Natl. Acad. Sci. USA</i> , November 1998;95: 13349-13351.
	X	Cartea et al., "Comparison of sense and antisense methodologies for modifying the fatty acid composition of <i>Arabidopsis thaliana</i> oilseed," <i>Plant Science</i> , 1998;136: 181-194.

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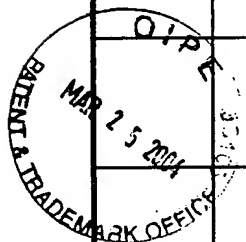
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	X	Cogoni et al., "Posttranscriptional Gene Silencing in <i>Neurospora</i> by a RecQ DNA Helicase," <i>Science</i> , 17 December 1999;286: 2342-2344.
	X	Cogoni et al., "Gene silencing in <i>Neurospora crassa</i> requires a protein homologous to RNA-dependent RNA polymerase," <i>Nature</i> , 13 May 1999; 399: 166-169.
	X	Crooke, Stanley T., <i>Antisense Research and Application</i> , Published by Springer-Verlang, Chapter 1: 1-50.
	X	Crystal Ronald G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , 1995; 270: 404-410.
	X	Ding et al., "Cell-to-Cell movement of potato spindle tuber viroid," <i>The Plant Journal</i> , 1997;12: 931-936.
	X	Dougherty et al., "Transgenes and gene suppression: telling us something new?," <i>Current Opinion in Cell Biology</i> , 1995;7: 399-405.
	X	Elbashir et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," <i>Nature</i> , May 24 2001;411(6836): 494-498.
	X	Fire et al., "Production of antisense RNA leads to effective and specific inhibition of gene expression in <i>C. elegans</i> muscle," <i>Development</i> , 1991;113: 503-514.
	X	Flavell, R.B., "Inactivation of gene expression in plants as a consequence of specific sequence duplication," <i>Proc. Natl. Acad. Sci. USA</i> , April 1994;91: 3490-3496.
	X	Friedmann, "Overcoming the Obstacles," <i>Scientific American</i> , June 1997: 96-101.
	X	Gale et al., "Translational Control of Viral Gene Expression in Eukaryotes," <i>Microbiology and Molecular Biology Reviews</i> , June 2000;64: 239-280.
	X	Ghislain et al., "The Interferon-Inducible Stat2:Stat1 Heterodimer Preferentially Binds <i>In Vitro</i> to a consensus Element Found in the Promoters of a Subset of Interferon-Stimulated Genes," <i>J of Interferon Cytokine Res.</i> , 2001;21: 379-388.
	X	Grant, Sarah R., "Dissecting the Mechanisms of Posttranscriptional Gene Silencing: Divide and Conquer," <i>Cell</i> , 5 February 1999;96: 303-306.

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	X	Hamilton et al., "A species of Small Antisense RNA in Posttranscriptional Gene Silencing in Plants," <i>Science</i> , 29 October 1999;286:950-952.
	X	Hamada et al., "Co-suppression of the hydrophobin gene <i>Hcf-1</i> is correlated with antisense RNA biosynthesis in <i>Cladosporium fulvum</i> ," <i>Mol Gen Genet.</i> , 1998;259: 630-638.
	X	Hartmann et al., "Activation of 2'-5' Oligoadenylate Synthetase by Single-stranded and Double-stranded RNA Aptamers," <i>Journal of Biological Chem.</i> , 6 February 1998;273(6): 3236-3246.
	X	Jaramillo et al., "The Interferon System: A review with Emphasis on the Role of PKR in Growth Control," <i>Cancer Invest.</i> , 1995;13(3): 327-338.
	X	Jensen et al., "Cosuppression of <i>I</i> Transposon Activity in <i>Drosophila</i> by <i>I</i> -Containing Sense and Antisense Transgenes," <i>Genetics</i> , December 1999;153: 1767-1774.
	X	Jorgensen et al., "An RNA-Based Information Superhighway in Plants," <i>Science</i> , 6 March 1998;279: 1486-1487.
	X	Ketting et al., " <i>mut-7</i> of <i>C. elegans</i> , Required for Transposon Silencing and RNA Interference, Is a Homolog of Werner Syndrome Helicase and RnaseD," <i>Cell</i> , 16 October 1999;99: 133-141.
	X	Kooter et al., "Listening to the silent genes: transgene silencing, gene regulation and pathogen control," <i>Trends in Plant Science</i> , September 1999;4(9): 340-347.
	X	Kumagai et al., "Cytoplasmic inhibition of carotenoid biosynthesis with virus-derived RNA," <i>Proc. Natl. Acad. Sci. USA</i> , February 1995;92: 1679-1683.
	X	Lindbo et al., "Induction of a Highly Specific Antiviral State in Transgenic Plants: Implications for Regulation of Gene Expression and Virus Resistance," <i>The Plant Cell</i> , December 1993;5: 1749-1759.
	X	Matzke et al., "Epigenetic silencing of plant transgenes as a consequence of divers cellular defence responses," <i>Cell Mol Life Sci</i> , 1998;54: 94-103.
	X	Metzlaff et al., "RNA-Mediated RNA Degradation and Chalocone Synthase A Silencing in <i>Petunia</i> ," <i>Cell</i> , March 21, 1997;88:845-854.

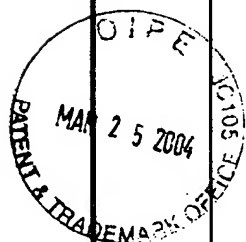


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	X	Misquitta et al., "Targeted disruption of gene function in <i>Drosophila</i> by RNA interference (RNA-i): A role for <i>nautilus</i> in embryonic somatic muscle formation," <i>Proc. Natl Acad. Sci. USA</i> , February 1999;96: 1451-1456.
	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus NM_030627, Accession No. NM_030621, "Homo sapiens Dicer1, Dcr-1 homolog ( <i>Drosophila</i> ) (Dicer1), transcript variant 2, mRNA" [online]. Bethesda, MD [retrieved on 2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=29294648&dopt=GenBank&term=NM_030621&qty=1>; 9 pgs.
	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus NM_148948, Accession No. NM_148948, "Mus musculus Dicer1, Dcr-1 homolog ( <i>Drosophila</i> ) (Dicer1), mRNA," [online]. Bethesda, MD [retrieved on 2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=22507358&dopt=GenBank&term=NM_148948&qty=1>; 6 pgs.
	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus NM_003733, Accession No. NM_003733, "Homo sapiens 2'-5'-oligoadenylate synthetase-like (OASL), transcript variant 1, mRNA," [online]. Bethesda, MD [retrieved on 2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=38016933&dopt=GenBank&term=NM_003733&qty=1>; 4 pgs.
	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus HUMP68A, Accession No. M35663, "Human p68 kinase mRNA, complete cds.," [online]. Bethesda, MD [retrieved on 2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=189505&dopt=GenBank&term=M35663&qty=1>; 3 pgs.



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	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus XM_010893, Accession No. XM_010893, "Homo sapiens signal transducer and activator of transcription 1, 91kD (STAT1), mRNA," [online]. Bethesda, MD [retrieved on 2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=20533804&dopt=GenBank&term=NLM_010893&qty=1>; 4 pgs.
	X	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Locus S72725, Accession No. S72725, "E2/NS1=envelope glycoprotein [hepatitis C virus HCV, agammaglobulinemic patient isolate, Genomic RNA, 441 nt]," [online]. Bethesda, MD [2003 December 19]. Retrieved from the Internet:<URL:www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=619405&dopt=GenBank&term=S72725&qty=1>; 2 pgs.
	X	Pachuk et al., "DNA vaccines-challenges in delivery," <i>Current Opinion in Molecular Therapeutics</i> , 2002;2(2): 188-198.
	X	Pachuk et al., "Characterization of a new class of DNA delivery complexes formed by the local anesthetic bupivacaine," <i>Biochim. Biophys. Acta</i> , 2000;1468: 20-30.
	X	Paddison et al., "Stable Suppression of gene expression by RNAi in mammalian cells," <i>Proc Natl Acad Sci USA</i> , 5 February 2002;99(3): 1443-1448.
	X	Palauqui et al., "Systemic acquired silencing: transgene-specific post-transcriptional silencing is transmitted by grafting from silenced stocks to non-silenced scions," <i>The EMBO Journal</i> , 1997;16(15): 4738-4745.
	X	Ratcliff et al., "A similarity Between Viral Defense and Gene Silencing in Plants," <i>Science</i> , 1997;276: 1558-1560.
	X	Romano et al., "Inhibition of Double-Stranded RNA-Dependent Protein Kinase PKR by Vaccinia Virus E3: Role of Complex Formation and the E3 N-Terminal Domain," <i>Molecular and Cellular Biology</i> , December 1998;18(12): 7304-7316.
	X	Ruiz et al., "Homology-dependent Gene Silencing in <i>Paramecium</i> ," <i>Molecular Biology of the Cell</i> , April 1998;9:931-943.

EXAMINER

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	X	Ruiz et al., "Initiation and Maintenance of Virus-Induced Gene Silencing," <i>The Plant Cell</i> , June 1998;10:937-946.
	X	Schiebel et al., "Isolation of an RNA-Directed RNA Polymerase-Specific CDNA Clone from Tomato," <i>The Plant Cell</i> , December 1998;10:2087-2101.
	X	Schofield et al., "Non-viral approaches to gene therapy," <i>British Medical Bulletin</i> , 1995;51(1): 56-71.
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<b>EXAMINER</b>	<b>Date Considered</b>
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	